

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8558

Bartle, C.J.

November 5, 2010

William Munce ("Mr. Munce" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Brent T. McLaurin, M.D., F.A.C.C., F.S.C.A.I. Dr. McLaurin is no stranger to this litigation. According to the Trust, he has signed at least 282 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated October 10, 2002, Dr. McLaurin attested in Part II of Mr. Munce's Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

compromise.³ Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits in the amount of \$959,751.⁴

In the report of claimant's echocardiogram, Dr. McLaurin stated that Mr. Munce's RJA/LAA measured 28%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Nancy V. Strahan, M.D., one of its auditing cardiologists.⁵ In audit, Dr. Strahan concluded that there was

3. Dr. McLaurin also attested that claimant suffered from New York Heart Association Functional Class IV symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level II benefits and "suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." See Settlement Agreement § IV.B.2.c.(5)(d). As the Trust does not contest the presence of sustained ventricular tachycardia which resulted in hemodynamic compromise, claimant must only establish that he qualified for Level II benefits. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.C.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject
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no reasonable medical basis for the attesting physician's finding that claimant suffered from moderate mitral regurgitation.

Specifically, Dr. Strahan stated that "[t]he degree of [mitral regurgitation] was either trivial or non-existent. Most of the planimetered [mitral regurgitant] jets were in fact back flow."

Based on the auditing cardiologist's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. Munce's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a declaration from Dr. McLaurin wherein he confirmed his finding that Mr. Munce suffered from moderate mitral regurgitation. Specifically, Dr. McLaurin stated that:

I originally interpreted [the] echocardiogram tape as showing moderate mitral regurgitation with a measured ratio of 28% (RJA/LAA). I have again reviewed the echocardiogram tape dated October 10, 2002, and I again find that the measurements provided on the tape appear accurate depicting a jet of moderate severity as determined by the Singh criteria. In addition, Mr. Munce has left atrial

5. (...continued)
to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Level V claim, the Trust audited Mr. Munce's claim pursuant to the PPP.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Munce's claim.

enlargement, left ventricular enlargement, and mildly elevated pulmonary pressures which are not uncommonly associated with significant mitral regurgitation. I stand by my findings as set forth in my echocardiogram report and [G]reen [F]orm [P]art [II] supporting a finding of moderate mitral regurgitation with a measured ratio of 28%.

I disagree with Dr. Nancy V. Strahan's finding that there was only trivial or non-existent mitral regurgitation evidenced in such echocardiogram tape. I also disagree with her findings regarding backflow. I specifically dispute her findings regarding the first issue.

The Trust then issued a final post-audit determination, again denying Mr. Munce's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust applied to the court for issuance of an Order to show cause why Mr. Munce's claim should be paid. On March 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6039 (Mar. 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of his claim, Mr. Munce reasserts the arguments made in contest; namely, that Dr. McLaurin's declaration provides sufficient evidence that claimant had moderate mitral regurgitation and therefore qualifies for Matrix Benefits.

In response, the Trust argues that claimant has failed to meet his burden of proof. Specifically, the Trust contends that Dr. McLaurin's declaration is insufficient to support his assertion that claimant suffered from moderate mitral regurgitation. The Trust further notes that claimant failed to meet his burden of proof because Dr. McLaurin did not identify a single, high-velocity, sustained jet of mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. As explained by Dr. Vigilante:

I measured the RJA and LAA in several ... cardiac cycles in which the mitral regurgitation jet appeared most impressive. Only mild mitral regurgitation was present on this study. The RJA/LAA ratio was much less than 12% on those cardiac cycles in which the mitral regurgitation jet appeared most impressive. The RJA/LAA ratio was much less than 10% in most of the cardiac cycles. The mitral regurgitation jet never came close to reaching the mid portion of the left atrium in any cardiac cycle. The sonographer measured 5 RJA's and LAA's on the tape. The first RJA was measured at 6.21 cm² with the LAA measuring 22.45 cm². This would calculate to a RJA/LAA ratio of 28%. This ratio of 28% is the same value as documented

by Dr. McLaurin in his formal echocardiogram report. The RJA value of 6.21 cm² is grossly inaccurate. Low velocity, non-mitral regurgitant jet flow accounted for more than half of this inaccurate RJA measurement. The other four RJA measurements on the echocardiogram tape were also inaccurate with low-velocity, non-mitral regurgitant jet flow noted within the tracings. There was no cardiac cycle in which the RJA/LAA ratio came close to 20%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of Dr. Strahan and Dr. Vigilante.⁸ Specifically, Dr. Strahan and Dr. Vigilante each concluded that claimant's echocardiogram did not demonstrate moderate mitral regurgitation. Rather than identify any particular error in the findings of Dr. Strahan and Dr. Vigilante, Mr. Munce relied on the declaration of Dr. McLaurin who simply confirmed his earlier finding and "disagree[d] with [Dr. Strahan]."⁹ Mere disagreement with the auditing cardiologist and the Technical Advisor is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

8. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

9. Dr. McLaurin's observation that "Mr. Munce has left atrial enlargement, left ventricular enlargement, and mildly elevated pulmonary pressures which are not uncommonly associated with significant mitral regurgitation" does not substitute for the explicit findings by the auditing cardiologist and the Technical Advisor that claimant does not have moderate mitral regurgitation.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

- (1) failing to review multiple loops and still frames;
- (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole;
- (4) over-manipulating echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;
- (7) failing to take a claimant's medical history; and
- (8) overtracing the amount of a claimant's regurgitation.

See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Strahan found that Dr. McLaurin relied on a jet that included backflow. In addition, Dr. Vigilante determined that Dr. McLaurin relied on "grossly inaccurate" measurements, explaining that "[l]ow velocity, non-mitral regurgitant jet flow accounted for more than half of this inaccurate RJA measurement." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Munce's claim for Matrix Benefits.